DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
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June 9, 2015

Applied Medical Technology, Inc.
Joshua D. Meinke
QA/Regulatory Supervisor
8006 Katherine Boulevard
Brecksville, OH 44141

Re: K150034
Trade/Device Name: AMT Enteral Transition Adapters
Regulation Number: 21 CFR§ 876.5980
Regulation Name: Gastrointestinal tube and accessories
Regulatory Class: II
Product Code: PIO
Dated: March 16, 2015
Received: March 18, 2015

Dear Joshua D. Meinke,

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies.

You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Herbert P. Lerner -S

for Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K150034

Device Name
AMT Enteral Transition Adapters

Indications for Use *(Describe)*
The AMT Enteral Transition Adapters are intended to facilitate enteral specific connections between AAMI/CN3(PS) compliant connectors and non ISO 80369-1 compliant legacy enteral connectors.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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SECTION – 5

510(K) Summary

AMT Enteral Transition Adapters

Date Prepared:	June 8, 2015
Submitter:	Joshua D. Meinke QA/Regulatory Supervisor Applied Medical Technology, Inc. 8006 Katherine Boulevard Brecksville, OH 44141 Phone: 440-717-4252 Fax: 440-717-4200 Email: Josh.Meinke@appliedmedical.net Contact Person: Joshua Meinke
Device Information:	Trade Name: AMT Enteral Transition Adapters Common Name: Enteral Transition Adapter Classification Name: Gastroenterology and Urology (21 CFR 876.5980) Regulatory Class: II Product Code: PIO FDA Identification: Facilitate enteral specific connections between AAMI/CN3(PS) compliant connectors and non ISO 80369-1 compliant legacy enteral connectors.
Predicate Device:	Enteral Specific Transition Connectors (Cedic S.R.L.) (cleared under K140581)
Indications for Use:	The AMT Enteral Transition Adapters are intended to facilitate enteral specific connections between AAMI/CN3(PS) compliant connectors and non ISO 80369-1 compliant legacy enteral connectors.
Device Description:	New standard ISO-80369-1 is pushing feeding tube manufacturers to transition current extension set designs to incorporate enteral only connectors. Most enteral feeding devices currently on the market utilize luer slip or catheter tip connectors to connect enteral giving sets and syringes to enteral receiving sets. Standard luer slip and catheter tip connectors raise risk levels for patients as devices outside of the enteral market use similar connections, including IVs. Therefore, the ISO/IEC 80369 series was developed to help reduce the possibility of misconnections across different medical fields.

	The FDA recently cleared an updated AMT enteral extension set in 510(k) K142989. This extension set remains identical to our previously marketed device, but includes Enfit connectors. However, launching a enteral extension sets with Enfit connectors will not be simultaneous across all manufacturers and distributors. Therefore, transition adapters are necessary for a limited time. As the new Enfit connectors are not backwards compatible with current luer and bolus connections currently used for enteral products, AMT has designed several transition adapter configurations to help users make the switch to the new connections. AMT estimates that there will be a time of at least a year and possibly up to three years where users and distributors will still have access to enteral devices with luer / bolus connectors. The transition adapters AMT has designed in this 510(k) will allow users to use their old giving/receiving sets until the market is flushed of old inventory. The AMT Enteral Transition Adapters come in 5 configurations and are made up of 5 separate components. The five configurations include: • Male Enfit to Male Luer Adapter • Female Enfit to Female Luer Adapter • Female Enfit to Y-Port (Bolus/Luer) Adapter • Female Enfit to Bolus Adapter • Male Enfit to Christmas-tree Adapter These 5 transition adapter configurations will allow AMT to offer users with options for all of the common enteral connectors currently on the market. All components and materials have been previously cleared in 510(k)s for similar use. It is planned to include these transition adapters kitted with enteral devices previously cleared through the 510(k) process, as well as selling the adapters as stand-alone items.
Technological Characteristics:	The AMT Enteral Transition Adapters are provided non-sterile for single user use only. They are made from DEHP and Latex free materials. The Enteral Transition Adapters are provided in a number of configurations providing different connection possibilities to enteral devices currently on the market. Description of the five different transition adapters AMT will offer are listed below: <u>Transition Adapter Types:</u> • Male Enfit to Male Luer Adapter (P/N: TRN101) • Female Enfit to Female Luer Adapter (P/N: TRN201) • Female Enfit to Y-Port (Bolus/Luer) Adapter) (P/N: TRN203) • Female Enfit to Bolus Adapter (P/N: TRN202) • Male Enfit to Christmas-tree Adapter (P/N: TRN102)
Biocompatibility Testing:	No additional biocompatibility testing was performed for this submission. The device and materials in finished form for the AMT Enteral Transition Adapters were previously tested under 510(k) K123716. All AMT Enteral Transition adapters have been tested for permanent (greater than 30 days) indirect mucosal contact, except for the Male Enfit to Christmas-tree Adapter (P/N: TRN 102) which has been tested to prolonged (less than 29 days) indirect mucosal contact.

Performance Testing:	AMT conducted various performance tests on all components contained within AMT Enteral Transition Adapters. The tests carried out included: • Tensile strength • Fluid leakage • Stress cracking • Resistance to separation from axial load • Resistance to separation from unscrewing • Resistance to overriding • Disconnection from unscrewing • Flow testing Incompatibility testing was conducted on the Enfit connectors as recommended in the ISO 80369-1 standard. Although the Enfit connectors will not misconnect to other connectors in the 80369 series, misconnections with non ISO/IEC 80369 series connectors may still occur.
Conclusions:	The AMT Enteral Transition Adapters are substantially equivalent to the predicate device cleared under K140581 in intended use, patient population, design, biocompatibility, testing criteria, and method of operation.